



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2010-0573; FRL-8865-2]

RIN 2070-AJ73

Benzidine-Based Chemical Substances; Di-*n*-pentyl phthalate (DnPP); and Alkanes, C₁₂₋₁₃, Chloro; Proposed Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA is proposing: To add nine benzidine-based chemical substances to the Significant New Use Rule (SNUR) on benzidine-based chemical substances; a SNUR for di-*n*-pentyl phthalate (DnPP) (1,2-benzenedicarboxylic acid, 1,2-dipentyl ester) (CAS No. 131-18-0); and a SNUR for alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6). In the case of the benzidine-based chemical substances, EPA is also proposing to make inapplicable the exemption relating to persons that import or process substances as part of an article. If finalized, this rule would require persons who intend to manufacture, import, or process these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance.

DATES: Comments must be received on or before *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0573, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA-HQ-OPPT-2010-0573. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

- *Instructions:* Direct your comments to docket ID number EPA-HQ-OPPT-2010-0573. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address

will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

- *Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Sara Kemme, National Program Chemicals Division (7404T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0511; email address: sara.kemme@epa.gov.

For general information contact: The TSCA Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

These three different SNURs may apply to different entities.

1. *Benzidine-based chemical substances.* You may be potentially affected by this action if you manufacture, import, or process, including as part of an article, any of the benzidine-based chemical substances listed in Tables 1. and 2. of the regulatory text in this document. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of one or more of the subject chemical substances.
- Entities which plan to use the listed chemical substances in conjunction with apparel and other finished products made from fabrics, leather, and similar materials.
- Entities which plan to use the listed chemical substances in conjunction with paper and allied products.

- Manufacturers, importers, or processors of the subject chemical substances in printing inks.

These entities may include those described by the North American Industrial Classification System (NAICS) codes 325-chemical manufacturing, 313-textile manufacturers, 316-leather and allied products manufacturers, 322-paper manufacturers, 4243-apparel, piece goods, and notions wholesalers, or 443-clothing and accessories stores.

2. *DnPP*. For DnPP, you may be potentially affected by this action if you manufacture (defined by statute to include import), or process DnPP. Potentially affected entities may include, but are not limited to: Chemical industry – plastic material & resins (NAICS code 325211).

3. *Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6)*. You may be potentially affected by this action if you manufacture, import, or process the following short-chained chlorinated paraffin (SCCP): Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6). Potentially affected entities may include, but are not limited to: Manufacturers (defined by statute to include importers) of SCCPs (NAICS codes 325 and 325998), e.g., chemical manufacturing; including miscellaneous chemical product and preparation manufacturing; and processors of SCCPs (NAICS codes 324 and 324191), e.g., petroleum lubricating oil and grease manufacturing.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To

determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5 for SNUR-related obligations and with respect to benzidine-based chemical substances, the applicability provisions in Unit II.C. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or

CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing to add nine chemical substances (see Table 1. in Unit III.A.) to the existing SNUR for certain benzidine-based chemical substances at § 721.1660. That regulation includes as significant new uses “any use other than as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573-58-0) as an indicator dye.” § 721.1660(a)(2). For the nine newly-proposed benzidine-based chemical substances, EPA is proposing to designate any use as a significant new use. EPA requests comment on whether there are any ongoing uses of these chemicals.

EPA is also proposing to amend the SNUR at § 721.1660 to make inapplicable the exemption at § 721.45(f) for persons that import or process benzidine-based chemical substances as part of an article.

Additionally, EPA is proposing a SNUR for DnPP that would designate, as a significant new use, any use of the substance other than as a chemical standard for laboratory use.

EPA is also proposing a SNUR for alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) that would designate any use of the substance as a significant new use. Because any use of alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) would be a new use, § 721.5(a)(2) would be inapplicable to alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6). This provision addresses manufacturers, importers, and processors who are also distributors of a chemical substance subject to a SNUR. In certain cases, it requires these distributors to alert their customers that the SNUR exists. This requirement serves an important

communication function when certain uses of a chemical, but not others, trigger Significant New Use Notice (SNUN) requirements. Where there are no ongoing, existing uses of a chemical substance and EPA determines by rule that all future uses trigger SNUNs requirement (as with alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6)), EPA believes these alerts are not only unnecessary, but unlikely to ever occur.

These proposed SNURs would require persons that manufacture, import, or process any of the chemicals for a significant new use, consistent with the requirements at § 721.25, to notify EPA at least 90 days before commencing such manufacture, process, or import of the chemical substance for a significant new use. For the benzidine-based chemical substances, the proposed elimination of the article exemption at § 721.45(f) would also require persons to notify EPA at least 90 days before commencing processing or importing as part of an article any of the currently-listed or newly-proposed benzidine-based chemical substances. The objectives and rationale for this proposed SNUR are explained in Unit VI.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). These factors include:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a SNUN to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). The general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6 or 7 to control the activities on which it has received the SNUN. If EPA does

not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

However, § 721.45(f) (which generally exempts persons importing or processing a substance as part of an article) would not apply to benzidine-based chemical substances listed at 40 CFR 721.1660 and those added by this proposed rule. Therefore, a person who imports or processes as part of an article a benzidine-based chemical substance that is covered by this proposed rule would not be exempt from submitting a SNUN. With respect to articles, it is still relevant to the rulemaking whether a use was ongoing or not at time of proposal. It is not EPA's intent to subject ongoing uses of any chemical substances to the requirements of a SNUR. Thus, to the extent that additional ongoing uses of benzidine-based chemical substances are found in the course of rulemaking (whether or not they involve importing or processing as part of articles), EPA would exclude those uses from the final SNUR.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

III. Overview of Benzidine-Based Chemical Substances

A. What Additional Benzidine-Based Chemical Substances are Subject to this Proposed SNUR?

This proposed rule would add nine benzidine-based chemical substances to the list of twenty-four chemical substances currently regulated under § 721.1660. The nine benzidine-based chemical substances covered by this proposed SNUR are listed in Table 1. The chemicals listed in Table 1. are identified by Chemical Abstract Service Registry Numbers (CAS number) or if the chemical's CAS number is claimed CBI, the chemical is identified by an EPA accession number, along with its corresponding generic name. The accession numbers are EPA assigned numbers used to identify chemicals in place of confidential CAS numbers. Table 1. also indicates the availability of the Colour Index (C.I.) name and C.I. number, which is either not available or CBI for some of the chemicals subject to this proposed rule. Persons who are interested in determining the precise identity of the chemical designated by a certain accession number and a generic name should submit a bonafide request to EPA that complies with the information requirements stipulated in § 721.11(b).

Table 1.—Newly Added Benzidine-Based Chemical Substances

CAS or accession number	C.I. name	C.I. number	Chemical name
117-33-9	Not available	Not available	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[2-[4'-[2-(4-hydroxyphenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-
65150-87-0	Not available	Not available	1,3,6-Naphthalenetrisulfonic acid, 8-hydroxy-7-[2-[4'-[2-(2-hydroxy-1-naphthalenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-, lithium salt (1:3)
68214-82-4	Direct Navy BH	Not available	2,7-Naphthalenedisulfonic acid, 5-amino-3-[2-[4'-[2-(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-4-hydroxy-, sodium salt (1:2)

72379-45-4	Not available	Not available	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[4'-[2-[2-hydroxy-4-[(2-methylphenyl)amino] phenyl]diazenyl]][1,1'-biphenyl]-4-yl]diazenyl]-6-(2-phenyldiazenyl)-
Accession No. 21808 CAS No. CBI (NA)	CBI	CBI	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy [[[substituted phenylamino]] substituted phenylazo] diphenyl]azo-, phenylazo-, disodium salt. (generic name)
Accession No. 24921 CAS No. CBI (NA)	CBI	CBI	4-(Substituted naphthalenyl)azo diphenyl azo-substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26256 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo-substituted carbopolycycloazo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26267 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo - substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26701 CAS No. CBI (NA)	CBI	CBI	Phenylazoaminohydroxynaphthalenylazobiphenylazo substituted benzene sodium sulfonate. (generic name)

B. What Action has the Agency Previously Taken on Other Benzidine-Based Chemical Substances?

In 1996, EPA promulgated a TSCA section 5(a)(2) SNUR for the benzidine-based chemical substances listed at § 721.1660 (61 FR 52287, October 7, 1996) (FRL-5396-6).

That rule considered any use of the chemical substances except those listed in

§ 721.1660(a)(2) as a significant new use that requires a SNUN to be submitted to the Agency prior to manufacture, import, or processing of the listed chemical substances.

Because they were identified as ongoing, the SNUR excluded as significant new uses the following uses: As a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; as a reagent for

detecting blood; and as an analytical standard. In addition, for Colour Index (C.I.) Direct Red 28 (Congo Red) (CAS No. 573-58-0), use as an indicator dye was excluded as a significant new use. The SNUR did not require a SNUN to be submitted by persons that import or process a listed substance as part of an article.

C. What is the Production Volume of Newly-Proposed and Currently-Listed Chemical Substances?

For the newly proposed nine benzidine-based chemical substances, data reported to EPA for the 2006, 2002, and 1998 reporting cycles, as required by the TSCA Inventory Update Reporting (IUR) rule, indicate no evidence of production (including import). The IUR regulation requires manufacturers and importers of certain chemical substances to report site and manufacturing information for chemicals manufactured (including imported) in amounts of 25,000 pounds or greater at a single site (prior to 2006, reporting was for 10,000 pounds at a site). A general market review on these chemical substances indicates no current manufacture (Ref. 1) within or outside the United States.

In addition, four of these benzidine-based chemicals were included in EPA's Benzidine-based Dyes Action Plan. The additional five chemicals were found in the confidential TSCA inventory. Designed as part of a comprehensive approach to enhancing EPA's Chemical Management Program, action plans summarize hazard, exposure, and use information; outline the potential risks that each chemical may pose; and identify the specific steps the Agency is considering to address those concerns (Ref. 2).

For the benzidine-based chemical substances currently listed at § 721.1660, data reported to EPA for the 2006, 2002, and 1998 reporting cycles, as required by the TSCA

IUR rule, indicate no evidence of domestic production (including import) at IUR reportable levels. Further, EPA's general market review on the currently listed benzidine-based chemical substances suggests that the majority of these chemical substances are not currently being manufactured domestically or abroad (Ref. 1). Although some of these substances appear to be manufactured for allowable uses within the United States at a level below current IUR reporting thresholds, and some substances appear to be manufactured outside the United States generally and may therefore potentially be imported as part of an article, EPA does not have information to suggest that the substances are being imported, for use as part of articles. In fact, the market review did not find evidence of any import of articles containing benzidine-based chemical substances. As stated in Unit VIII., EPA welcomes comments on any aspect of this proposed SNUR. The Agency specifically invites comments on whether there is ongoing manufacture, import, or processing of these benzidine-based chemical substances, including in articles, other than as excepted at § 721.1660(a)(2).

D. What are the Uses of these Benzidine-Based Chemical Substances?

Historically, the benzidine-based chemical substances currently listed at § 721.1660 were used as reagents, biological stains in laboratories, and in food industries. Note that TSCA section 3(2)(B)(vi) excludes foods, food additives, drugs, cosmetics or devices (as defined in the Federal Food, Drug, and Cosmetic Act) from the statutory definition of a "chemical substance" when such substances are manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. Additionally, these previously listed benzidine-based substances are believed to have been historically used as dyes in the textile industry.

The nine newly-proposed benzidine-based chemical substances are believed to have been used in the past in the production of textiles, paints, printing inks paper, and pharmaceuticals. However, based on market information and the fact that the 2006 IUR had no production reports for any of the benzidine-based chemical substances, if these chemical substances are used at all, they are likely used in small volumes, making it difficult to access current production and use information.

E. What are the Potential Health Effects of these Chemicals?

The 1980 EPA Preliminary Risk Assessment on derivatives of benzidine established that the primary hazard concern was for the carcinogenic effects to humans from exposure to specific metabolites of the chemical substances (Ref. 3). There is potential for benzidine-based chemical substances to metabolize to the parent benzidine molecule, which is a known carcinogen (Refs. 4, 5, and 6). This metabolism occurs in humans by an enzyme-mediated reaction. These enzymes are found in the liver, in gut bacteria, and in skin bacteria. The result of this enzymatically-aided reduction is the release of the carcinogenic aromatic amine from the chemical substance. Studies have demonstrated that the reduction of benzidine-based chemical substances occurs in the human body as well as on the skin (Ref. 7). Therefore, the primary human health concern for consumers is exposure to the benzidine-based chemical substances through oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis (Ref. 8). Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults (Ref. 8). For additional information see Benzidine-Based Chemical Substances; Significant New Uses of Certain Chemical Substances; Final Rule (61 FR 52287, October 7, 1996).

F. What are the Potential Routes and Sources of Exposures to These Chemicals?

There are benzidine related exposure concerns as a result of the use of benzidine and benzidine-based chemical substances. In 1996, EPA identified inhalation, skin absorption, and ingestion as possible routes of exposure in a variety of settings where benzidine-based chemical substances are either manufactured or used (61 FR 52287, October 7, 1996). Although EPA estimated that the highest exposure would be to workers who were involved in dye manufacturing, EPA determined that it was necessary to apply the SNUR to any use of the listed benzidine-based chemical substances, with the exception of the limited uses mentioned in Unit II.A. EPA listed all the benzidine-based chemical substances that it was able to identify on the TSCA Inventory at that time. Since then, EPA has identified the nine additional benzidine-based chemical substances listed as part of Table 1. and has similar concerns about potential consumer and worker exposure to these substances.

Dermal exposure can occur from the leaching of the chemical substances by sweat in contact with the dyed textiles (Ref. 7). Dermal exposure is also a concern since many of these chemical substances can be directly absorbed by the skin to some extent. It is well established that the enzymatically-aided dye reduction to the carcinogenic benzidine unit occurs internally in the liver and the gut (Refs. 9 and 10). Studies have shown that some human skin bacteria possess azo-reductases, the enzymes necessary to break down the benzidine-based chemical substances to release the carcinogenic amines, which can be more readily absorbed (Ref. 11).

Consistent with the information on dermal absorption that EPA reviewed in developing its recent Benzidine-based Chemical Substances Action Plan (EPA-HQ-

OPPT-2010-0570 at <http://www.regulations.gov>), EPA identified the following main routes of consumer exposure to benzidine-based chemical substances that are of concern: (1) Dermal absorption, the primary route from wearing dyed clothing or footwear; (2) oral ingestion, an additional route for babies and young children who suck on clothing, blankets, and other non-food products which might contain any of the benzidine-base chemical substances; (3) inhalation exposure, a more prevalent route in occupational settings; however, it can also occur from the use of dyed inks during “air brushing” or from off-gassing from the dyed carpets to indoor air; and (4) contact with the benzidine-based chemical substances entering the environment, through the whole life cycle of benzidine-based chemical substances in textiles (Ref. 12).

IV. Overview of DnPP

A. What Chemical is Included in the Proposed SNUR?

This proposed SNUR would apply to DnPP (1,2-Benzenedicarboxylic acid, 1,2-dipentyl ester), CAS No. 131-18-0, an ortho-phthalate (or phthalate ester).

B. What is the Production Volume of DnPP?

No IUR production volume data were reported for DnPP during the 2006, 2002, 1998, and 1994 reporting cycles (Ref. 13). The last reporting of DnPP production to the IUR occurred in 1990 and corresponds to the lowest reportable production volume range (10,000 to 500,000 pounds) (Ref. 13).

DnPP was included in EPA’s Phthalates Action Plan, which was issued on December 30, 2009 (Ref. 14a). As stated in Unit III.C., the chemical action plans were designed as a part of a comprehensive approach to enhancing EPA’s Chemical Management Program. These action plans summarize available hazard, exposure, and

use information; outline the potential risks that each chemical may present; and identify the specific steps the Agency is considering to address those concerns. Please note that in response to a request for correction of the information provided in the 2009 Phthalate Action Plan that was filed under the Agency's Information Quality Guidelines by the American Chemistry Council, EPA issued a revised Phthalate Action Plan on March 14, 2012 (Ref. 14b). Copies of the request for correction and EPA's response to it are available at <http://www.epa.gov/quality/informationguidelines/iqg-list.html>.

Internet queries performed by EPA identified several companies that either use or sell DnPP as a chemical standard for laboratory use. As a result, EPA is proposing a SNUR for DnPP, excluding use of the substance as a chemical standard for laboratory use.

C. What are the Uses of DnPP?

DnPP belongs to a broad category of chemicals commonly referred to as phthalates. Although a number of phthalates are in common use, EPA believes the individual phthalate DnPP is not in general use in the United States, and only has a limited application as a chemical standard for laboratory use. As a chemical category, the major use of phthalates is as plasticizers (Refs. 15-23) especially in polyvinyl chloride (PVC) products, where they are added to impart flexibility and other desirable properties. Phthalate-containing PVC products include a variety of industrial and commercial products, as well as specialized medical and dental applications. The particular phthalate or combination of phthalates used in a specific product's formulation depends on the properties the phthalates impart, as well as their cost.

D. What are the Potential Health and Environmental Effects of DnPP?

1. *Human health effects.* Exposures of some phthalates in animal studies resulted in phthalate syndrome effects, which consist of changes in the fetal development of the reproductive system (Refs. 15-22 and 24-35). The phthalates that are the most potent at causing phthalate syndrome effects are generally those with linear ester side chains having 4-6 carbons (Ref. 24). DnPP has a linear carbon chain length of 5 carbons. Of the phthalates studied, DnPP is the most potent in producing testicular toxicity in pubertal animals (Ref. 24).

Developmental oral exposures in rats to DnPP showed increased resorptions, increased fetal mortality, and decreased fetal testicular testosterone production (Refs. 36 and 37); and reduced anogenital distance in male rat offspring (Ref. 38). Effects noted in adult mice exposed to DnPP include decreased body weight; increased liver weights; decreased kidney weights; decreases in the weights of the epididymis, cauda epididymis, testes, and seminal vesicles; complete absence of detectable sperm; shorter average estrous cycle length in females; and decreased fertility (Refs. 39 and 40). Gross and microscopic evidence of degenerative changes have been observed in the testes and epididymis (including testicular atrophy, interstitial cell hyperplasia, degeneration of the seminiferous tubules, and accumulation of fluid and degenerated cells in the epididymis) of rodents (Refs. 39 and 40). There are no subchronic or chronic animal studies of DnPP exposure through any exposure route.

There are no known human studies of exposure to DnPP. However, due to the data discussed in this section, the data presented and discussed in Phthalates and Cumulative Risk Assessment: The Tasks Ahead, Committee on the Health Risks of Phthalates, National Research Council (2008) (Ref. 24) and DnPP's general structure and

categorization as a phthalate, EPA notes that the human health effects of DnPP exposure may be similar to that observed for some other phthalates. Several human studies have reported associations of exposure of some other phthalates with adverse reproductive outcomes and developmental effects similar to those in the rat, although no causal link has been established (Refs. 24 and 41-50). The reproductive developmental effects of some phthalates observed in humans include shortened anogenital distance observed in newborn boys, shortened pregnancy, lower sex and thyroid hormones, and reduced sperm quality in adults; however, some studies failed to show these effects (Ref. 42). Since the pathway for sexual differentiation in the fetus is highly conserved in all mammals, the reproductive and developmental effects observed in the rat studies are potentially relevant to humans.

Studies in animals evaluating the cumulative effects of combinations of phthalates on testosterone fetal mortality, and male and female reproductive development later in life have demonstrated all mixtures were cumulative for all endpoints (Refs. 36-37 and 51-55). The reproductive effects of DnPP observed in animal studies, the reproductive effects of other phthalates observed in humans, and the data on the cumulative effects of mixtures of phthalates, support EPA's concern for potential human health hazards following exposure to DnPP.

2. *Environmental effects.* EPA does not know of any studies of the environmental effects of DnPP. Due to the general structure of DnPP, its behavior in an aquatic environment similar to the close analog mono 2-ethylhexyl phthalate, its log K_{ow} , and water solubility measurements, and its categorization as a phthalate, EPA is concerned that the environmental effects of DnPP may be similar to those of other

phthalates studied. Other phthalates studied have been shown to have biological effects in all studied animal groups and have been observed at environmentally relevant exposures in the nanogram/liter to microgram/liter range. The combination of the inherent toxicity, variable solubility, log of the octanol-water coefficient values, and bioconcentration factor (BCF) values among the studied phthalates elicit both acute and chronic toxicity to aquatic and terrestrial wildlife by targeting thyroid function, liver function, reproduction, and other physiological mechanisms (Refs. 31-35, 56 and 57).

E. What are the Potential Routes and Sources of Exposure to DnPP?

1. *Human exposure.* Data from the National Health and Nutrition Examination Survey (NHANES) indicates widespread exposure of the general population to various phthalates (Ref. 58). Phthalates are used in a wide array of plastic products and may be released into the environment during use and disposal of these products (Ref. 58).

Biomonitoring data from amniotic fluid and urine have demonstrated that humans are exposed to various phthalates *in utero*, as infants, during puberty, and in adult life; and that people are exposed to several phthalates at once. The urinary metabolites of DnPP were not specifically included in the 4th National Report on Human Exposure to Environmental Chemicals (2010), so EPA cannot draw conclusions as to the current exposure of the general population in the United States to DnPP.

2. *Environmental exposure.* Due to phthalates' pervasive use and release, as well as their propensity for global transport, various phthalates may be found in most environmental media, including ambient air, surface water, soil, and sediment (Refs. 25-32 and 34-35). Fish and other aquatic organisms, as well as terrestrial animals have

evidenced exposure to a common phthalate: di-(2-ethylhexyl) phthalate (DEHP) (Refs. 34 and 57). EPA does not have available data on environmental exposures to DnPP.

V. Overview of Alkanes, C₁₂₋₁₃, Chloro (CAS No. 71011-12-6)

A. What Chemical is Included in the Proposed SNUR?

This proposed SNUR would cover alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6), one type of short-chain chlorinated paraffin (SCCP). This consists of C₁₂ and C₁₃ alkanes with varying degrees of chlorination.

B. What is the Production Volume of Alkanes, C₁₂₋₁₃, Chloro (CAS No. 71011-12-6)?

No production volumes for alkanes, C₁₂₋₁₃ chloro (CAS No. 71011-12-6) were reported to the IUR during the 2006, 2002, 1998, and 1994 reporting cycles, and EPA found no additional evidence of any importation or manufacturing of the chemical.

Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) was included in EPA's Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins Action Plan (Ref. 59). As stated in Unit III.C., the chemical action plans were designed as a part of a comprehensive approach to enhancing EPA's Chemical Management Program. These action plans summarize available hazard, exposure, and use information; outline the potential risks that each chemical may present; and identify the specific steps the Agency is considering to address those concerns.

C. What Were the Uses of this SCCP?

Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) is an individual chemical substance that belongs to a category of chemicals referred to as SCCPs. There are many different chemical substances that are members of the SCCP category. Generally these SCCPs

have between 10 and 13 carbon atoms and contain 40 – 70 percent chlorine by weight. Of the different SCCPs that are listed on the TSCA Inventory, EPA believes the SCCP named “Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6)” is not in use in the United States and EPA has found no information that indicates it has ever been used. All of the data discussed in this section associated with the SCCPs general category would pertain to any individual member of that category, including alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6).

D. What are the Potential Environmental Effects of Alkanes, C₁₂₋₁₃, Chloro (CAS No. 71011-12-6)?

The primary concern for SCCPs is ecotoxicity. There are internationally accepted data specifically on the ecotoxicity of alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) (Ref. 60). Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) are highly toxic to aquatic invertebrates following acute and chronic exposures. In fish, this high toxicity is associated with chronic exposures, but not for acute exposures. For aquatic plants, there is high toxicity associated with both acute and chronic exposures to SCCPs in general (Ref. 59-61).

Both Health Canada and Environment Canada have characterized all chlorinated paraffins (short chain chlorinated paraffins, medium chain chlorinated paraffins, and long chain chlorinated paraffins), which include the chemical substance covered by this proposed rule, as “toxic” under the Canadian Environmental Protection Act (CEPA) (Ref. 61). Their assessment found that these SCCPs have or may have an immediate or long term harmful effect on the environment or its biological diversity; and that they are

persistent, bioaccumulative, inherently toxic and present in the environment primarily as a result of human activity (Ref. 61).

E. What are the Potential Routes and Sources of Exposure to Alkanes, C₁₂₋₁₃, Chloro (CAS No. 71011-12-6)?

The mechanisms or pathways by which the SCCPs, including alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6), move into and through the environment and humans are not fully understood, but are likely to include releases from manufacturing of the chemicals, manufacturing of products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (e.g., disposal, recycling).

EPA has concerns regarding the environmental fate and the exposure pathways that lead to any SCCP presence, including C12 and C13 SCCPs (for example, Alkanes, C₁₂₋₁₃, Chloro (CAS No. 71011-12-6)), in a variety of biota, including freshwater aquatic species, marine mammals, and avian and terrestrial wildlife (Ref. 60). In addition, SCCPs, including C12 and C13 SCCPs, have been detected in samples of human breast milk from Canada and the United Kingdom, as well as in a variety of food items from Japan and various regions of Europe (Ref. 62-63). SCCPs are routinely found in soil and sediment samples. EPA also has concerns about the persistence, bioaccumulation, and toxicity (PBT) of SCCPs (Ref. 60).

VI. Rationale and Objectives

A. Rationale

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

1. *Benzidine-based chemical substances.* As summarized in Unit III., EPA is concerned about potential carcinogenic effects on workers and consumers from the manufacture, processing, importing, or use of these substances. Consumers exposed via dermal exposure to consumer products containing the benzidine-based chemical substances are a particular concern because enzymes present in the human body and in bacteria on the skin aid in the reduction of these chemical substances to the benzidine unit, an established human carcinogen (Ref. 8). The main consumer products that could result in dermal exposure if containing these chemical substances include textiles and leather products because they are in prolonged contact with human skin.

During the review of information on benzidine-based chemical substances, EPA determined that the newly identified chemical substances covered by this proposed rule present the same concerns (Ref. 2) as those of the benzidine-based chemical substances currently listed under § 721.1660. However, based on a review of IUR data and a

separate market review, EPA does not believe there is any current manufacture of these nine benzidine-based chemical substances within or outside the United States.

In addition, as discussed earlier, although some of the currently listed benzidine-based chemical substances may be manufactured or processed outside the United States, EPA does not have specific information that suggests they are entering into the United States in imported articles (Ref. 4). In fact, an analysis of the benzidine-based chemical substances market (Ref. 1) revealed no information indicating import of articles containing benzidine-based chemical substances for non-excluded purposes. Supporting a conclusion that there is no import of textile articles containing benzidine-based chemical substances, the American Apparel and Footwear Association, the national trade association representing apparel, footwear, and other sewn products companies and their suppliers, which compete in the global market, includes benzidine on its Restricted Substances List (RSL) (Ref. 64). The RSL is a compilation of chemicals, regulated or banned, that are used by apparel and footwear industries.

Although it appears there is no ongoing manufacture of the nine newly proposed benzidine-based chemical substances, or import for a non-excluded use of articles containing any benzidine-based chemical substances, the manufacture (including import) or processing of the nine newly proposed benzidine-based chemical substances and the import or processing of articles containing any benzidine-based chemical substances may begin at any time, without prior notice to EPA. Thus, EPA is concerned that commencement of the manufacture, import, or processing for any new uses, including resumption of past uses, of benzidine-based chemical substances could significantly increase the magnitude and duration of exposure to humans over that which would

otherwise exist currently. EPA is concerned that such an increase should not occur without an opportunity to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance.

Therefore, EPA is proposing a SNUR for the nine benzidine-based chemical substances by adding them to those currently listed at § 721.1660, and to make inapplicable the article exemption at § 721.45(f) for those chemical substances newly proposed in this rulemaking as well as for those already listed at § 721.1660. If finalized, a person who intends to manufacture (including import) or process any of the benzidine-based chemical substances for a non-excluded use, or to import or process any listed benzidine-based chemical substance for a non-excluded use as part of an article, would be required to submit a SNUN.

2. *DnPP*. As summarized in Unit IV., EPA has concerns regarding potential adverse human health and environmental effects that may be caused by DnPP. EPA has direct information from animal studies that DnPP specifically can elicit developmental/reproductive effects that are relevant to human health and also indicate potential effects in wildlife. EPA also is concerned that due to its general structure and categorization as a phthalate that DnPP may elicit adverse environmental effects similar to those described for other phthalates. EPA is concerned that any manufacturing (including import) or processing of DnPP, beyond that for its limited ongoing use as a chemical standard for laboratory use, could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist currently. EPA is concerned that such an increase should not occur without an opportunity to evaluate

activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance. Therefore, EPA is proposing a SNUR for DnPP that would designate, as a significant new use, any use of the chemical substance other than as a chemical standard for laboratory use. If finalized, a person who intends to manufacture, import, or process DnPP for use other than as a chemical standard for laboratory use would be required to submit a SNUN.

3. *Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6)*. The mechanisms or pathways by which the SCCPs, including alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6), move into and through the environment and humans are not fully understood, but are likely to include releases from manufacturing of the chemicals, manufacturing of products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (e.g., disposal, recycling).

EPA believes that all manufacture, processing, and import into the United States of alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) has ceased. Given EPA has no evidence to suggest that there is any manufacture, processing, or importation of this chemical substance in the United States, and taking into consideration the negative commercial and regulatory environment associated with this chemical internationally (including the EU and Canadian ban on marketing) and use of the alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) domestically, EPA does not expect to find such activity. However, EPA is concerned that commencement of the manufacture, import or processing for any new uses, including resumption of past uses, could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist. EPA is concerned that such an increase should not occur without an opportunity to evaluate activities

associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance. Therefore, EPA is proposing a SNUR for alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) that would designate as a significant new use any use of the chemical substance. If finalized, a person who intends to manufacture, import, or process alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) for any use would be required to submit a SNUN.

EPA is requesting comment on whether any of the significant new uses identified are currently ongoing. However, if EPA determines, based on comments on this proposed rule or on other information the Agency identifies, that any proposed significant new use of any of the chemical substances has been ongoing (including, in the case of benzidine-based chemical substances, that an article containing benzidine-based chemical substances was being imported or processed) prior to date of publication of the final rule, EPA would exclude such ongoing uses from the final SNUR and consider pursuing other regulatory action, as appropriate.

B. Objectives

Based on the considerations in Unit VI.A.1-3, EPA wants to achieve the following objectives with regard to the significant new use(s) that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture or process the specified chemicals for the described significant new uses before that activity begins;
2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing of the specified chemicals for the described significant new use; and

3. EPA would be able to regulate prospective uses of the specified chemicals before the described significant new uses occur, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7.

VII. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of the benzidine-based chemical substances subject to this proposed rule, DnPP and the alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6), as discussed herein, EPA considered relevant information about the toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA has preliminarily determined that the manufacture, import, processing, or import or

processing as part of an article of any of the benzidine-based chemical substances subject to this proposed rule, except ongoing uses specified in § 721.1660(a)(2)(i) of the regulatory text in this document, is a significant new use. EPA has also preliminarily determined that the manufacture, import, or processing of DnPP for any use other than as a chemical standard for laboratory use is a significant new use, and the manufacture, processing, or import of alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) for any use is a significant new use.

VIII. Request for Public Comment

EPA welcomes comments on any aspect of this proposed SNUR. Information available about environmental effects, health effects, and exposure would be beneficial. EPA is also requesting public comment on whether there are any ongoing uses of any of these chemicals for the proposed significant new uses (including processing or import of benzidine-based chemical substances in articles) and would welcome specific information that documents such uses.

IX. Alternatives

Before proposing these SNURs, EPA considered the following alternative regulatory actions:

A. Promulgate a TSCA Section 8(a) Reporting Rule

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture, import, or process a listed chemical for a specific use or any use. However, for the chemical substances subject to this proposed rule, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require

reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements. In view of the level of health and environmental concerns about the chemicals subject to this proposed rule if used for the proposed significant new uses, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

B. Regulate Under TSCA Section 6

EPA may regulate under TSCA section 6 if “the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment.” (TSCA section 6(a)). Given that the benzidine-based chemical substances subject to this proposed rule are no longer being used except as provided in the regulatory text of this document, DnPP is no longer being used except as a chemical standard for laboratory use, and alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) is no longer used in the United States, EPA concluded that risk management action under TSCA section 6 is not necessary at this time. This proposed SNUR would allow the Agency to address the potential risks associated with the proposed significant new uses. If EPA learns that these chemicals are in use, EPA may reconsider this decision and pursue additional regulatory action as appropriate.

X. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin the commercial manufacture, import, or processing of a covered substance as a significant new use have to cease any such activity as of the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses. To the extent that additional ongoing uses are found in the course of rulemaking, EPA would exclude those uses from the final SNUR. EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

XI. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. There are two exceptions: 1) Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)) and 2) development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)). In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); § 721.25, and § 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, import, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA would take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance.
2. Potential benefits of the chemical substance.

3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

XII. SNUN Submissions

According to 40 CFR § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

XIII. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of these chemicals and for articles containing any of the benzidine-based chemical substances included in this proposed rule. These economic analyses, which are briefly summarized here, are available in the docket for this proposed rule.

The costs of submission of a SNUN would be incurred when a company decides to pursue a significant new use of one of these chemicals. In the event that a SNUN is submitted, costs are estimated at approximately \$8,112 per SNUN submission, and include the cost for preparing and submitting the SNUN, recordkeeping, and the payment of a user fee. Businesses that submit a SNUN are either subject to a \$2,500 user fee required by § 700.45(b)(2)(iii), or, if they are a small business with annual sales of less

than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (§ 700.45(b)(1)). In its evaluation of this proposed rule, EPA also considered the potential costs a company might incur by avoiding or delaying the significant new use in the future, but these costs have not been quantified.

B. Export Notification

EPA regulations under TSCA section 12(b) (15 U.S.C. 2611(b)) at 40 CFR part 707, subpart D require that, for chemicals subject to a proposed or final SNUR, a company notify EPA of the first export or intended export to a particular country of an affected chemical substance. EPA estimated that the one-time cost of preparing and submitting an export notification to be \$78.54. The total costs of export notification would vary per chemical, depending on the number of required notifications (i.e., number of countries to which the chemical is exported).

XIV. References

As indicated under **ADDRESSES**, a docket has been established for this proposed rule under docket ID number EPA-HQ-OPPT-2010-0573. The following is a listing of the documents that have been placed in the docket for this proposed rule. The docket includes information considered by EPA in developing this proposed rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, please consult the technical person listed under **FOR FURTHER**

INFORMATION CONTACT. The docket is available for review as specified under **ADDRESSES.**

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14 b. U.S. EPA, 2012. U.S. Environmental Protection Agency. Phthalates Action Plan (Revised).

<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates.html>.

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Available at: <http://www.nicnas.gov.au/Publications/CAR/Other/Phthalates.asp>

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XV. Statutory and Executive Order Reviews

A. Regulatory Planning and Review

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) determined that this proposed SNUR is a “significant regulatory action” under section 3(f) of the

Executive Order. Accordingly, EPA submitted this action to OMB for review under Executive Order 12866 and 13563, entitled *Improving Regulation and Regulatory Review* (76 FR 3821, January 21, 2011). EPA prepared an analysis of the potential costs and benefits associated with this action, which is summarized in Unit XIII.

Changes made in response to OMB recommendations have been documented in the docket for this rulemaking as required by section 6(a)(3)(E) of the Executive Order.

B. Paperwork Activities

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9 and included on the related collection instrument, or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070-0038 (EPA ICR No. 1188). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average 97 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated

collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Small Entity Impacts

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that promulgation of this SNUR would not have a significant adverse economic impact on a substantial number of small entities. Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. Small entity is defined in accordance with section 601 of the RFA as: A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

For purposes of assessing the impacts of this proposed rule on small entities, EPA has determined that this proposed rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency estimated potential impacts on small business. A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." By definition of the word "new" and based on all information currently available to EPA, it appears that no small or large entities presently engage in such

activity. Since this action would require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact would occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be.

EPA's experience to date is that, in response to the promulgation of over 1,000 SNURs, the Agency receives on average only five notices per year. Of those SNUNs submitted, only one appears to be from a small entity in response to any SNUR. Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. State, Local, and Tribal Governments

In EPA's experience with proposing and finalizing SNURs since 1980, no state, local, or Tribal government has initiated the manufacture of a chemical for a new use. Furthermore, EPA does not have any reason to believe that any state, local, or tribal government would do so for the chemicals in this rulemaking. For that reason, EPA has determined that this action does not have federalism implications as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), or tribal

implications as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000).

In addition, this action does not impose any enforceable duty or contain any unfunded mandate for State, local, or tribal governments under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531-1538. Nor does it otherwise have any effect on small governments, or estimated impacts on the private sector that might exceed \$100 million in any year.

Thus, sections 202, 203, 204, or 205 of UMRA, Executive Order 13132, and Executive Order 13175 do not apply to this action.

E. Protection of Children

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this action is not an economically significant regulatory action as defined by Executive Order 12866, and it is not intended to address environmental health or safety risks for children.

F. Effect on Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not an economically significant regulatory action as defined by Executive Order 12866, and it is not expected to affect energy supply, distribution, or use.

G. Technical Standards

Since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), 15 U.S.C. 272 note, does not apply to this action.

H. Environmental Justice

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: March 20, 2012.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Revise § 721.1660 to read as follows:

§ 721.1660 Benzidine-based chemical substances.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The benzidine-based chemical substances listed in Table 1. and Table 2. of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

Table 1.—Newly Added Benzidine-Based Chemical Substances

CAS or accession number	C.I. name	C.I. number	Chemical name
117-33-9	Not available	Not available	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[2-[4'-[2-(4-hydroxyphenyl)diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-
65150-87-0	Not available	Not available	1,3,6-Naphthalenetrisulfonic acid, 8-hydroxy-7-[2-[4'-[2-(2-hydroxy-1-naphthalenyl)diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-, lithium salt (1:3)
68214-82-4	Direct Navy BH	22590	2,7-Naphthalenedisulfonic acid, 5-amino-3-[2-[4'-[2-(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-4-hydroxy-, sodium salt (1:2)
72379-45-4	Not available	Not available	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[4'-[2-[2-hydroxy-4-[(2-methylphenyl)amino] phenyl]diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-6-(2-phenyldiazenyl)-
Accession No. 21808 CAS No. CBI (NA)	CBI	CBI	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy [[[substituted phenylamino]] substituted phenylazo] diphenyl]azo-, phenylazo-, disodium salt. (generic name)
Accession No. 24921	CBI	CBI	4-(Substituted naphthalenyl) azo diphenyl azo-substituted carbopolycycle azo benzenesulfonic

CAS No. CBI (NA)			acid, sodium salt. (generic name)
Accession No. 26256 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo-substituted carbopolycycloazo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26267 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo - substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26701 CAS No. CBI (NA)	CBI	CBI	Phenylazoaminohydroxynaphthalenylazobiphenylazo substituted benzene sodium sulfonate. (generic name)

Table 2.—Benzidine-Based Chemical Substances

CAS number	C.I. name	C.I. number	Chemical name
92–87–5	Benzidine	Not available	[1,1'-Biphenyl]-4,4'-diamine
531–85–1	Benzidine · 2HCl	Not available	[1,1'-Biphenyl]-4,4'-diamine, dihydrochloride
573–58–0	C.I. Direct Red 28	22120	1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt
1937–37–7	C.I. Direct Black 38	30235	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl) azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2302–97–8	C.I. Direct Red 44	22500	1-Naphthalenesulfonic acid, 8,8'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[7-hydroxy-, disodium salt
2429–73–4	C.I. Direct Blue 2	22590	2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt
2429–79–0	C.I. Direct Orange 8	22130	Benzoic acid, 5-[[4'-[(1-amino-4-sulfo-2-naphthalenyl) azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–81–4	C.I. Direct Brown 31	35660	Benzoic acid, 5-[[4'-[[2,6-diamino-3-[[8-hydroxy-3,6-disulfo-7-[(4-sulfo-1-naphthalenyl)azo]-2-naphthalenyl]azo]-5-methylphenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, tetrasodium salt
2429–82–5	C.I. Direct Brown 2	22311	Benzoic acid, 5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl) azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–83–6	Direct Black 4	30245	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diamino-5-methylphenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)-, disodium salt
2429–84–7	C.I. Direct Red 1	22310	Benzoic acid, 5-[[4'-[(2-amino-8-hydroxy-6-sulfo-

			1-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2586-58-5	C.I. Direct Brown 1:2	30110	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2602-46-2	C.I. Direct Blue 6	22610	2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
2893-80-3	C.I. Direct Brown 6	30140	Benzoic acid, 5-[[4'-[[2,4-dihydroxy-3-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
3530-19-6	C.I. Direct Red 37	22240	1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt
3567-65-5	C.I. Acid Red 85	22245	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4'-[(4-methylphenyl)sulfonyl]oxy]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt
3626-28-6	C.I. Direct Green 1	30280	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt
3811-71-0	C.I. Direct Brown 1	30045	Benzoic acid, 5-[[4'-[[2,4-diamino-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
4335-09-5	C.I. Direct Green 6	30295	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt
6358-80-1	C.I. Acid Black 94	30336	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[[4-hydroxy-2-[(2-methylphenyl)amino]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-6-[(4-sulfophenyl)azo]-, trisodium salt
6360-29-8	C.I. Direct Brown 27	31725	Benzoic acid, 5-[[4'-[[4-[(4-amino-7-sulfo-1-naphthalenyl)azo]-6-sulfo-1-naphthalenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, trisodium salt
6360-54-9	C.I. Direct Brown 154	30120	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-3-methyl-, disodium salt
8014-91-3	C.I. Direct Brown 74	36300	Benzoic acid, 3,3'-[(3,7-disulfo-1,5-naphthalenediyl)bis[azo(6-hydroxy-3,1-phenylene)azo[6(or7)-sulfo-4,1-naphthalenediyl]azo[1,1'-biphenyl]-4,4'-diylazo]]bis[6-hydroxy-, hexasodium salt
16071-86-6	C.I. Direct	30145	Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-

	Brown 95		hydroxy-5-sulfophenyl)azo]phenyl] azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxybenzoato(4-)-, disodium salt
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(2) The significant new uses are:

(i) Any use other than use as:

(A) For the chemicals listed in Table 2., as reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood and as an analytical standard.

(B) For Colour Index (C.I.) Direct Red 28 (Congo Red) (CAS No. 573-58-0) listed in Table 2., as an indicator dye.

(ii) For the 9 chemical substances listed in Table 1.: Any use.

(3) *Revocation of article exemption.* The provisions of § 721.45(f) do not apply to this section. A person who imports or processes the chemical substances identified in paragraph (a)(1) of this section as part of an article for the significant new use described in paragraph (a)(2) of this section must submit a significant new use notice.

(b) [Reserved]

3. Add § 721.10226 to subpart E to read as follows:

§ 721.10226 Di-*n*-pentyl phthalate (DnPP).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as di-*n*-pentyl phthalate (DnPP) (1,2-benzenedicarboxylic acid, 1,2-dipentyl ester) (CAS No. 131-18-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is: Any use other than as a chemical standard for laboratory use.

(b) [Reserved]

4. Add § 721.10227 to subpart E to read as follows:

§ 721.10227 Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is: Any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Persons who must report.* § 721.5 applies to this section except for § 721.5(a)(2). A person who intends to manufacture or import for commercial purposes a substance identified in paragraph (a)(1) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]